

Remarks

I. SUMMARY

Claims 1-3, 7-8, and 21-26 are pending in the present application. Claims 27-29 directed to a non-elected invention are canceled herein. Claims 1-3, 7-8, and 21-26 are directed to compositions for treating osteoporosis.

Claims 1-3 and 7-8 were rejected in the December 14, 2006 final Office Action.

II. REJECTION UNDER 37 CFR §1.142(b) and MPEP §821.03

Claims 7-8 and 27-29 stand rejected under 37 CFR §1.142 (b) and MPEP §821.03 as allegedly being directed to a non-election invention. Claims 27-29 are canceled herein without prejudice. The Action asserts that the Claims 7-8 directed to a composition for treating osteoporosis comprising an organic solvent extract product of culture of *Cordyceps sinensis*, wherein at least one organic solvent is diethyl ether, are distinct from the originally elected invention, which encompassed the species election of the water extract of the claim-designated ingredient of *Cordyceps sinensis*. Applicants respectfully traverse this rejection and request withdrawal thereof in view of the following remarks.

In the present invention, the water extract of the claim-designated ingredient of *Cordyceps sinensis* is actually prepared from the organic solvent extract product of *Cordyceps sinensis*. By way of example, the claim-designated ingredient of *Cordyceps sinensis* is prepared by extracting a culture of *Cordyceps sinensis* using diethyl ether, followed by methanol and final water extraction. Accordingly, Claims 7-8 are believed to be directed to the originally elected invention. Withdrawal of the rejection and consideration of all pending claims, are respectfully requested.

III. CLAIM OBJECTIONS

The claims have been amended as suggested by the Examiner to correct the error in spelling "Cordyceps." Accordingly, withdrawal of the objection is respectfully requested.

IV. REJECTION UNDER 35 U.S.C. §102(b)

Claims 1-3 as amended, stand rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Tadetomo et al. and Yoshii. The Action asserts that the claimed functional effects are inherent to the extract taught by Tadetomo and Yoshii because the fungus and the part of the fungus used in the making of the *Cordyceps sinensis* extract are one and the same as disclosed in the claimed invention (see Page 4-5, Office Action). Applicants respectfully traverse this rejection and request withdrawal thereof in view of the following remarks.

Applicants respectfully submit that Tadetomo and Yoshii neither teach nor suggest the presently claimed invention. Tadetomo discloses a composition comprising a dried powder of culture of mycelium of *Cordyceps sinensis* prepared from **hot-water extraction**. Yoshii discloses a composition comprising a dried powder of culture of mycelium of *Cordyceps sinensis* prepared by **baking and pulverizing**.

In contrast, the present invention is directed to a composition comprising a dried powder of culture of mycelium of *Cordyceps sinensis* prepared by **organic solvent extraction using diethyl ether followed by water extraction**. Tadetomo and Yoshii neither teach nor suggest water extraction using organic solvents. In addition, Applicants respectfully submit that the content of the water extract prepared by prior organic solvent extraction is different from that prepared by water extraction only.

Applicants submit herewith a Declaration in support of this paper, which further demonstrates that the water extract obtained by the present method is different from that obtained without prior organic solvent extraction, and thus, Tadetomo and Yoshii do not inherently anticipate the present compositions. In the Declaration, Applicants prepared water extracts with or without using a diethyl ether solvent. Both extracts were analyzed by GPC HPLC. The detailed experimental procedure is set forth in the Declaration. Water extract prepared according to the present invention is denoted as "CS(ether, MeOH, H₂O)" and water extract prepared without prior organic solvent extraction is denoted as "CS(H₂O)". As set forth in the Declaration, *e.g.*, in the profiles of GPC HPLC (having differing peaks), the content of the water extract of the present invention is different from that prepared without prior organic solvent extraction particularly in molecule size. There is plenty of substance with high molecular weight in

CS(ether, MeOH, H₂O), whereas most substance in CS(H₂O) are small size molecules. Because of the different content, Applicants respectfully submit that Tadetomo and Yoshii do not inherently anticipate the present compositions.

Moreover, Tadetomo teaches the referenced fungal extract as a composition with cardiotonic, hypotensive, antitussive, and anti-fatigue effects. Yoshii teaches the referenced fungal extract as a composition as a health food mixed with animal milk. Tadetomo and Yoshii neither teach nor suggest the referenced fungal extract as a composition for treating osteoporosis or as a composition for suppressing the decrease of spongy bone density.

Because Tadetomo and Yoshii fails to teach or suggest the presently claimed extract compositions and use thereof, Applicants respectfully submit that Tadetomo and Yoshii do not anticipate the present invention. The U.S.C. §102(b) rejection is believed to be overcome and withdrawal of the rejection is requested.

Further, the claim 1 is amended herein to explicitly specify that the dried powder comprises a water extract of an organic solvent extract product of culture of *Cordyceps sinensis*. No new matter is believed to be introduced by the amendment. Applicants submit that the present claim amendment overcomes the 35 U.S.C. §102(b) rejection and withdrawal of the rejection is requested.

V. REJECTION UNDER 35 U.S.C. §102(a)

Claims 1-2 as amended, stand rejected under 35 U.S.C. §102(a) as allegedly being anticipated by Li et al. The Action asserts that the claimed functional effect is inherent to the extract taught by Li because the fungus used in the making of the Li's composition is one and the same as disclosed in the claimed invention (see Page 5-6, Office Action). Applicants respectfully traverse this rejection and request withdrawal thereof in view of the following remarks.

Applicants respectfully submit that Li neither teaches nor suggests the presently claimed invention. Li discloses a composition comprising a dried powder of nature *Cordyceps sinensis* prepared by **baking, grinding, and sieving**. The part of the fungus used in the making of the Li's composition is not explicitly mentioned. However, the "fruit body" is the medicinal part of the

Cordyceps sinensis used in Chinese medicine. Accordingly, Applicants respectfully submit that the fruit body is the part of the fungus used in the making of the Li's composition.

In contrast, the present invention is directed to a composition comprising a dried powder of **culture** of **mycelium** of *Cordyceps sinensis* prepared by organic solvent extraction using diethyl ether, followed by methanol and water extraction. Li neither teaches nor suggests that the mycelium is the effective part and the referenced fungal extract can be obtained by organic and water extraction.

Moreover, Li's composition with effects of calcium replenishment, immune function regulation, chaotic internal secretion regulation, strengthening, and osteoporosis treatment, etc., is used in "compound prescription" (medicine made of two or more ingredients). No direct and circumstantial evidence can prove that the dried powder of culture of *Cordyceps sinensis* is the effective ingredient for treating osteoporosis in Li's composition. Additionally, low percentage of *Cordyceps sinensis* extract (lower than 0.3 wt. %) is used in Li's composition.

Li neither teaches nor suggests that the referenced fungal extract has the effect of treating osteoporosis by suppressing a decrease of spongy bone density.

Accordingly, for at least these reasons, Applicants respectfully submit that Li does not anticipate the present claims. The 35 U.S.C. §102(a) rejection is believed to be overcome and withdrawal of the rejection is respectfully requested.

VI. PROVISIONAL OBVIOUSNESS-TYPE DOUBLE PATENTING REJECTION

Claims 1-3, as amended, stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as allegedly being unpatenable over claims 1-3, 9 and 10 of copending Application No. 11/533,655. Applicants are submitting a terminal disclaimer herewith to obviate the rejection. Accordingly, withdrawal of the objection is requested.

VII. CONCLUSION


In view of the amendments to the claims and the arguments presented, Applicants respectfully submit that the present claims are patentable in view of the cited references, and are in condition for allowance. Therefore, Applicants respectfully request withdrawal of each rejection and allowance of the present application.

If any extensions of time are necessary to prevent abandonment of this application, then extensions of time are hereby petitioned for under 37 C.F.R. §1.136(a). The USPTO is hereby authorized to charge the Terminal Disclaimer fee and any other required fees, including fees for net addition of claims, to deposit account number 50-3120.

Should the Examiner believe that further discussion of any remaining issues would advance the prosecution, she is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,

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